

REMARKS

Claims 1-10 have been canceled.

Claim 11 has been amended to indicate that the viscosity refers to the biomaterial comprising the crosslinked derivative. Support can be found in paragraphs [0061] and [0465].

No new matter has been added.

Claim Amendment

The Examiner states on page 3 of the Office Action that the claims reciting viscosity are construed as “wherein said *biomaterial comprising the* cross-linked derivative has a viscosity of [viscosity value].” The Examiner states that this interpretation is consistent with the Specification and suggests that this interpretation is the only way in which the viscosity element of the claims is not superfluous. The Examiner also indicates that an amendment to the claims to this effect should be considered.

Applicants have amended the claims according to the Examiner’s suggestion, but state that this amendment does not change the scope of the claim in any way. The Examiner is correct that the Specification supports interpretation of the claims in this context. Consequently, the amendment does not narrow the claims in any way.

Double Patenting

The Examiner has rejected claims 11 and 16-30 for nonstatutory obviousness-type double patenting over claims 11-15 and 6 of US Patent No. 6,723,709 in view of Della Valle (EP 341

745). Applicants attach hereto an executed Terminal Disclaimer, thereby overcoming the rejection.

The Examiner has rejected claims 11 and 16-30 for nonstatutory obviousness-type double patenting over claims 11, 12, 15, 16, 21 and 22 of US Patent No. 7,202,230 ('230) in view of Della Valle (EP 341 745). Specifically, the Examiner states that the claims of '230 are drawn to a surgical method comprising the application of a biomaterial comprising 3-10% autocrosslinked hyaluronic acid and synthetic polymers, such as PTFE, and a pharmacologically active substance such as anti-inflammatory agents, wherein the biomaterials may be in the form of films, gels, etc. The Examiner acknowledges that the claims do not teach any particular molecular weight or viscosity or a crosslinking range as narrow as the instant claims nor do they recite inhibition of surgical adhesions.

With respect to Della Valle (EP 341745), the Examiner states that Della Valle teaches a crosslinked product and the preparation of the product using a hyaluronic acid having an average molecular weight of about 250, 000 to about 350,000. The Examiner then concludes that it would have been obvious to one having ordinary skill in the art to prepare the crosslinked product recited in the claims with a hyaluronic acid having the molecular weight as suggested by Della Valle with a reasonable expectation of success. She also contends that one of skill in the art would optimize the viscosity and crosslinking through routine experimentation with a reasonable expectation of success. Applicants respectfully traverse.

First, Applicants note that they have previously stated that the Della Valle reference, while disclosing autocrosslinked hyaluronic acid derivatives, provides no guidance as to the

degree of viscosity that is necessary to achieve fewer adhesions than the untreated controls. In fact, the Della Valle patent does not even contain the term “viscosity.”

Second, Applicants submit that the Examiner’s contention that a skilled artisan would have a reasonable expectation of success in optimizing viscosity and degree of crosslinking via routine experimentation must be viewed in the context of the knowledge in the field at the time of the invention. That is, if the field of art did not recognize any advantage to a particular degree of crosslinking or to a particular level of viscosity, the skilled artisan would not even be bothered to attempt optimization.

The Examiner herself has already established that the teachings of Huang represent the knowledge in this field of art at the time of the invention (see Office Action of June 18, 2007, pages 3-6). But as discussed in the Zanellato Declaration of record and on pages 9-11 of its accompanying amendment (submitted October 18, 2008), the knowledge or belief in the field at the time of the invention was that the percent of adhesions was independent of a crosslinked gel’s viscosity. In other words, at the time of the invention those of skill in the art believed that viscosity data were irrelevant in optimizing a product to prevent adhesions. Because those skilled in the art believed that only the degree of crosslinking mattered, as evidenced by Huang, and because Della Valle teaches only the preparation of a 5% hyaluronic crosslinked gel (i.e. there is no discussion of viscosity), the skilled artisan would not even consider optimizing a property that was deemed to have no relevance, let alone hold a reasonable belief of success. It is only in Study 8, as Dr. Zanellato points out, where the role of viscosity in adhesion prevention is determined. Thus, the fact that viscosity is a critical feature presents an unexpected and improved result that evidences the instant invention’s nonobviousness.

Application No. 10/812,587
Amendment dated July 9, 2008
Reply to Office Action of April 9, 2008

Docket No.: 2039-0124PUS2

In view of the above, Applicants respectfully request reconsideration and removal of the non-statutory obviousness-type double patenting rejection.

Conclusion

In view of the above remarks, all the claims remaining in the case as amended are submitted as defining novel, non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested..

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Susan W. Gorman (Reg. No. 47,604) in San Diego, CA at telephone number 858-792-8855 to conduct an Interview in an effort to expedite prosecution in connection with the present application.

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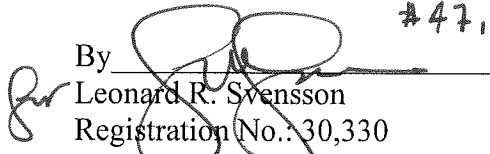
Docket No.: 2039-0124PUS2

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Dated: July 9, 2008

Respectfully submitted,

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